Appl. No. 09/719,662 Amdt. dated September 2, 2003 Reply to Advisory Action of May 23, 2003

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

Claims 1-33 (canceled).

- 1 Claim 34. (currently amended): A pharmaceutical aerosol foam composition comprising:
- 2 petrolatum in an amount of approximately 10 to 50% by weight, based on the total weight
- 3 of the composition;
- 4 an aqueous solvent;
- 5 an organic cosolvent,
- an effective amount of clobetasol proprionate propionate, wherein said clobetasol
- 7 proprionate propionate is solubilized in the composition.
- 1 Claim 35. (new): A pharmaceutical aerosol foam composition comprising:
- 2 an effective amount of a pharmaceutically active ingredient;
- 3 an occlusive agent;
- 4 an aqueous solvent;
- 5 an organic cosolvent; and
- an emulsifier component in an amount wherein the ratio of emulsifier component to a
- 7 combination of the occlusive agent, pharmaceutically active ingredient, and organic cosolvent is
- 8 about 1:5 to about 1:8;
- 9 the pharmaceutically active ingredient being insoluble in both water and the occlusive
- 10 agent;
- the occlusive agent being present in an amount sufficient to form an occlusive layer on
- 12 the skin, in use.
- 1 Claim 36. (new): The pharmaceutical aerosol foam composition according to Claim 35,
- 2 wherein the occlusive agent is petrolatum.
- 1 Claim 37. (new): The pharmaceutical foam composition according to Claim 35 or Claim
- 2 36, wherein the water insoluble pharmaceutically active ingredient is selected from the group



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- 3 consisting of an analgesic, anti-inflammatory agent, antifungal, antibacterial, anesthetic,
- 4 xanthine, sex hormone, antiviral, antipruritic, antihistamine and corticosteroid.
- 1 Claim 38. (new): The pharmaceutical aerosol foam composition according to Claim 37,
- 2 wherein the pharmaceutically active ingredient is a corticosteroid selected from the group
- 3 consisting of betamethasone valerate and clobetasol propionate.
- 1 Claim 39. (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, wherein the pharmaceutically active ingredient is present in an amount of from
- approximately 0.005% by weight to approximately 10% by weight, based on the total weight of
- 4 the pharmaceutical aerosol foam composition.
- 1 Claim 40. (new): The pharmaceutical aerosol foam composition according to Claim 35,
- 2 wherein the occlusive agent is selected from the group consisting of a mineral oil and grease, a
- 3 long chain acid, an animal fat and grease, a vegetable fat and grease and a water insoluble
- 4 polymer.
- 1 Claim 41. (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, wherein the occlusive agent is present in an amount of approximately 55% by weight
- 3 or less, based on the total weight of the composition.
- 1 Claim 42. (new): The pharmaceutical aerosol foam composition according to Claim 41,
- 2 wherein the occlusive agent is present in an amount of approximately 10 to 50% by weight,
- 3 based on the total weight of the composition.
- 1 Claim 43. (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, wherein the emulsifier component is selected from the group consisting of a non-
- 3 ionic, cationic or anionic surfactant, a fatty alcohol, a fatty acid and fatty acid salts thereof.
- 1 Claim 44. (new): The pharmaceutical aerosol foam composition according to Claim 43,
- 2 wherein the emulsifier component includes a mixture of a sorbitan ester and a polyoxyethylene
- 3 fatty alcohol ether.



- (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, wherein the emulsifier component is present in an amount of from approximately 1 to
- 3 15% by weight, based on the total weight of the composition.
- 1 Claim 46. (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, wherein the aqueous solvent is present in an amount of from approximately 25 to 95%
- 3 by weight, based on the total weight of the composition.
- 1 Claim 47. (new): The pharmaceutical aerosol composition according to Claim 35 or Claim
- 2 36, wherein the organic cosolvent is present in an amount from approximately 0.25% by weight
- 3 to 50% by weight, based on the total weight of the composition.
- 1 Claim 48. (new): The pharmaceutical aerosol foam composition according to Claim 47
- wherein the organic cosolvent is an alkyl benzoate.
- 1 Claim 49. (new): The pharmaceutical aerosol foam composition according to Claim 35 or
- 2 Claim 36, further including an effective amount of an aerosol propellant.
- 1 Claim 50. (new): The pharmaceutical aerosol foam composition according to Claim 49,
- 2 wherein the aerosol propellant is a hydrocarbon and is present in an amount of from
- 3 approximately 2.5 to 20% by weight, based on the total weight of the composition.
- 1 Claim 51. (new): A pharmaceutical aerosol dispenser comprising:
- 2 a pharmaceutical aerosol foam composition including
- an effective amount of a pharmaceutically active ingredient;
- 4 an occlusive agent;
- 5 an aqueous solvent;
- 6 an organic cosolvent; and
- an emulsifier component in an amount wherein the ratio of emulsifier component to a
- 8 combination of the occlusive agent, pharmaceutically active ingredient, and organic cosolvent is
- 9 about 1:5 to about 1:8;
- the pharmaceutically active ingredient being insoluble in both water and the occlusive
- 11 agent;



- the occlusive agent being present in an amount sufficient to form an occlusive layer on the skin, in use.
- 1 Claim 52. (new): A pharmaceutical aerosol foam composition consisting essentially of:
- 2 an effective amount of a pharmaceutically active ingredient;
- 3 an occlusive agent;
- 4 an aqueous solvent;
- 5 an organic cosolvent; and
- 6 the pharmaceutically active ingredient being insoluble in both water and the occlusive
- 7 agent;
- 8 the occlusive agent being present in an amount sufficient to form an occlusive layer on
- 9 the skin, in use.
- 1 Claim 53. (new): The pharmaceutical aerosol foam composition according to Claim 52,
- 2 wherein the occlusive agent is petrolatum.
- 1 Claim 54. (new): The pharmaceutical foam composition according to Claim 52 or Claim
- 2 53, wherein the water insoluble pharmaceutically active ingredient is selected from the group
- 3 consisting of an analgesic, an anti-inflammatory agent, an antifungal, an antibacterial, an
- 4 anesthetic, a xanthine, a sex hormone, an antiviral, an antipruritic, an antihistamine and a
- 5 corticosteroid.
- 1 Claim 55. (new): The pharmaceutical aerosol foam composition according to Claim 37,
- 2 wherein the pharmaceutically active ingredient is a corticosteroid selected from one or more of
- 3 the group consisting of betamethasone valerate and clobetasol propionate.
- 1 Claim 56. (new): The pharmaceutical aerosol foam composition according to Claim 52 or
- 2 Claim 53, wherein the pharmaceutically active ingredient is present in amounts of from
- 3 approximately 0.005% by weight to approximately 10% by weight, based on the total weight of
- 4 the pharmaceutical aerosol foam composition.



- 1 Claim 57. (new): The pharmaceutical aerosol foam composition according to Claim 52,
- 2 wherein the occlusive agent is selected from the group consisting of a mineral oil and grease, a
- 3 long chain acid, an animal fat and grease, a vegetable fat and grease and a water insoluble
- 4 polymer.
- 1 Claim 58. (new): The pharmaceutical aerosol foam composition according to Claim 52 or
- 2 Claim 53, wherein the occlusive agent is present in an amount of approximately 55% by weight
- 3 or less, based on the total weight of the composition.
- 1 Claim 59. (new): The pharmaceutical aerosol foam composition according to Claim 58,
- 2 wherein the occlusive agent is present in an amount of approximately 10 to 50% by weight,
- 3 based on the total weight of the composition.
- 1 Claim 60. (new): The pharmaceutical aerosol foam composition according to Claim 52 or
- 2 Claim 53, further including an effective amount of an emulsifier component.
- 1 Claim 61. (new): The pharmaceutical aerosol foam composition according to Claim 60,
- 2 wherein the emulsifier component is selected from the group consisting of a non-ionic, cationic
- 3 or anionic surfactant, a fatty alcohol, a fatty acids and fatty acid salts thereof.
- 1 Claim 62. (new): The pharmaceutical aerosol foam composition according to Claim 61,
- 2 wherein the emulsifier component includes a mixture of a sorbitan ester and a polyoxyethylene
- 3 fatty alcohol ether.
- 1 Claim 63. (new): The pharmaceutical aerosol foam composition according to Claim 60,
- 2 wherein the emulsifier component is present in an amount of from approximately 1 to 15% by
- 3 weight, based on the total weight of the composition.
- 1 Claim 64. (new): The pharmaceutical aerosol foam composition according to Claim 52 or
- 2 Claim 53, wherein the aqueous solvent is present in an amount of from approximately 25 to 95%
- 3 by weight, based on the total weight of the composition.



- 1 Claim 65. (new): The pharmaceutical aerosol composition according to Claim 52 or Claim
- 2 53, wherein the organic cosolvent is present in an amount from approximately 0.25% by weight
- 3 to 50% by weight, based on the total weight of the composition.
- 1 Claim 66. (new): The pharmaceutical aerosol foam composition according to Claim 65
- 2 wherein the organic cosolvent is an alkyl benzoate.
- 1 Claim 67. (new): The pharmaceutical aerosol foam composition according to Claim 52 or
- 2 Claim 53, further including an effective amount of an aerosol propellant.
- 1 Claim 68. (new): The pharmaceutical aerosol foam composition according to Claim 67,
- 2 wherein the aerosol propellant is a hydrocarbon and is present in an amount of from
- 3 approximately 2.5 to 20% by weight, based on the total weight of the composition.
- 1 Claim 69. (new): A pharmaceutical aerosol dispenser comprising a pharmaceutical aerosol
- 2 foam composition, said composition consisting essentially of:
- an effective amount of a pharmaceutically active ingredient
- 4 an occlusive agent;
- 5 an aqueous solvent;
- 6 an organic cosolvent; and
- 7 the pharmaceutically active ingredient being insoluble in both water and the occlusive
- 8 agent;
- 9 the occlusive agent being present in an amount sufficient to form an occlusive layer on
- 10 the skin, in use.
- 1 Claim 70. (new): The pharmaceutical aerosol dispenser of Claim 69, wherein said foam
- 2 composition further includes an effective amount of an emulsifier component.
- 1 Claim 71. (new): A pharmaceutical aerosol foam composition comprising:
- 2 an effective amount of a corticosteroid;
- an occlusive agent;
- 4 an aqueous solvent;



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the composition.

5	an organic cosolvent; and
6	the pharmaceutically active ingredient being insoluble in both water and the occlusive
7	agent;
8	the occlusive agent being present in an amount sufficient to form an occlusive layer on
9	the skin, in use.
10	
1	Claim 72. (new) The pharmaceutical aerosol foam composition according to Claim 71,
2	further comprising an emulsifier component in an amount of from approximately 1 to 15% by
3	weight, based on the total weight of the composition.
1	Claim 73. (New): A pharmaceutical aerosol foam composition comprising:
1	Claim 73. (110w). 11 pharmaceutical acrosor toam composition comprising.
2	an occlusive agent in an amount up to 50% by weight, based on the total weight of the
3	composition;
4	an aqueous solvent;
5	an organic cosolvent,

an effective amount of clobetasol propionate, wherein said clobetasol propionate is solubilized in